



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/567,659 | 09/07/2006 | Fiona Campbell | 007193-19 US | 2462 |
| 36234 7590 10/06/2008 THE MCCALLUM LAW FIRM, P. C. 685 BRIGGS STREET PO BOX 929 ERIE, CO 80516 | | | | |
| EXAMINER | | | | |
| SOROUSH, ALI | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1616 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 10/06/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,659

Applicant(s)

CAMPBELL ET AL.

Examiner

ALI SOROUSH

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 25 and 37-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 25 and 37-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

In a preliminary amendment filed on 06/13/2007 applicant has amended claims 13 and 25 and cancelled claims 14-24 and 26-36. Therefore, claims 1-13, 25, and 37-60 are currently pending examination for patentability.

NOTE: Claim numbers in claims 13 and 25 have been lined through by error. The said claims are considered pending and not cancelled. Corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 53-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52, 53, 55, 56, 58 and 59 recite the limitation "The method of claim 50" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 59 recites the limitation "wherein the bacteria is" in line 1. There is insufficient antecedent basis for this limitation in the claim.

For claims 53-60 the examiner has construed the claims to be composition claims and will apply art as such.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 50, 52, 53, 59 and 60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicant claims a milk product with a mucolytic agent present and indicates that iodine (See Specification page 12, Line 15) is one such mucolytic agent. Hemling (Iodine in Milk, Published 10/18/2001) teaches that "lactating women secrete milk with 60 to 281 μ g/l iodine" (See page 1, paragraph 4) and also indicates that commercial (bovine) milk also contains an amount of iodine. (See page 3, Table 3). Also, Dial et al. (Antibiotic Properties of Bovine Lactoferrin on *Helicobacter pylori*, Published 1998) indicates that bovine colostrum contains lactoferrin which has antibiotic properties against *H. pylori*. (See title and page 2754, column 2, Lines 10-14). Therefore, claims 50, 52, 53, 59, and 60 are directed to naturally occurring product which is not patentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 8, 12, 13, 25, 37, 38, 40, 41, 43, 45, and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Casswall et al. (Bovine Anti-*Helicobacter pylori* Antibodies for Oral Immunotherapy, Published 2002) as evidenced by Hemling (Iodine

in Milk, Published 10/18/2001) and Dial et al. (Antibiotic Properties of Bovine Lactoferrin on *Helicobacter pylori*, Published 1998).

Caswall et al. teach, "An anti-*H. pylori* bovine colostral hyperimmune immunoglobulin preparation (BIC) was generated and its efficacy was tested in different *in vitro* experiments ..." (See abstract). "Milk or colostrum from cows immunized with different antigens has previously been shown to be an effective and safe source of orally administered antibodies for both prophylaxis and therapy ... Hence, we produced a bovine immunoglobulin colostral preparation (BIC), which was used in therapeutic experiments in a *H. pylori* mouse model." (See page 1380, column 2, Lines 11-19 and page 1381, column 1, Lines 1-2). "The ability of the BIC to block the binding of *H. pylori* to gastric tissue *in situ* was compared with other bovine colostrum Ig preparations." (See page 1381, column 1, Lines 9-13). "The BIC preparation was then compared with a control preparation from non-immunized cows for its inhibition of binding of *H. pylori* to human gastric mucosa *in situ*. Almost 90% of blocking was observed when 0.1 mg/mL of the BIC was preincubated with *H. pylori* before incubation with human gastric mucosa tissue sections. BIC (1mg/mL) completely blocked the binding." (See page 1382, column 2, Lines 39-47). Caswell et al. further teach, "Much interest is currently focused on *Helicobacter pylori* infection and its association with development of gastritis, peptic ulcers and gastric malignancies in humans." (See page 1380, column 1, Lines 1-4). Caswell et al. conclude that "Bovine colostral antibodies against *H. pylori* can be generated in high titres, inhibit binding *in vitro* and can eradicate or reduce the number of bacteria in infected mice." (See abstract).

With regard to the composition comprising a mucolytic agent Hemling teaches that "lactating women secrete milk with 60 to 281 μ g/l iodine" (See page 1, paragraph 4) and also indicates that commercial (bovine) milk also contains an amount of iodine. (See page 3, Table 3). Since applicant indicates iodine (See Specification page 12, Line 15) is one such mucolytic agent and therefore drinking the composition taught by Caswell et al. would necessarily result in inhibition and/ or reduction of bacterial colonization of mucous epithelium, reduction of damage to mucous epithelium associated with bacterial infection, and treat a disease or condition associated with bacterial infection of mucous epithelium.

With regard to the composition comprising lactoferrin, Dial et al. indicates that bovine colostrum contains lactoferrin which has antibiotic properties against *H. pylori*. (See title and page 2754, column 2, Lines 10-14). Therefore, the composition of Caswell et al. inherently has lactoferrin and antibiotic activity against *H. pylori*. For the foregoing reasons the instant claims are anticipated by the prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 5, 7, 9, 10, 11, 39, 42, 46, 47, 48, 51, 54, 55, 56, 57, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casswall et al. (Bovine Anti-Helicobacter pylori Antibodies for Oral Immunotherapy, Published 2002) in view of Burggraber et al. (US Patent Application 2003/0180381 A1, Published 09/25/2003) and as evidenced by Dial et al. (Antibiotic Properties of Bovine Lactoferrin on Helicobacter pylori, Published 1998).

Applicant Claims

Applicant claims method of inhibiting bacterial colonization of mucous epithelium, reducing bacterial infection of mucous epithelium, reducing damage to mucous epithelium associated with bacterial infection, and method for treating a disease or condition associated with bacterial infection of mucous epithelium by administering a composition comprising a mucolytic agent and a milk product. Applicant further claims the aforementioned composition.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Casswall et al. teach, "An anti-H. pylori bovine colostral hyperimmune immunoglobulin preparation (BIC) was generated and its efficacy was tested in different in vitro experiments ..." (See abstract). "Milk or colostrum from cows immunized with different antigens has previously been shown to be an effective and safe source of orally administered antibodies for both prophylaxis and therapy ... Hence, we produced a bovine immunoglobulin colostral preparation (BIC), which was used in therapeutic experiments in a H. pylori mouse model." (See page 1380, column 2, Lines 11-19 and page 1381, column 1, Lines 1-2). "The ability of the BIC to block the binding of H. pylori to gastric tissue in situ was compared with other bovine colostrum Ig preparations." (See page 1381, column 1, Lines 9-13). "The BIC preparation was then compared with a control preparation from non-immunized cows for its inhibition of binding of H. pylori to human gastric mucosa in situ. Almost 90% of blocking was observed when 0.1 mg/mL of the BIC was preincubated with H. pylori before incubation with human gastric mucosa tissue sections. BIC (1mg/mL) completely blocked the binding." (See page 1382, column 2, Lines 39-47). Caswell et al. further teach, "Much interest is currently focused on Helicobacter pylori infection and its association with development of gastritis, peptic ulcers and gastric malignancies in humans." (See page 1380, column 1, Lines 1-4). Caswell et al. conclude that "Bovine colostral antibodies against H. pylori can be generated in high titres, inhibit binding in vitro and can eradicate or reduce the number of bacteria in infected mice." (See abstract).

Dial et al. teach that bovine colostrum contains lactoferrin which has antibiotic properties against H. pylori. (See title and page 2754, column 2, Lines 10-14).

Bruggraber et al. teach, "Cobalt salts have been found to be particularly effective against *H. pylori* and may therefore be used to treat gastrointestinal infection with this bacteria ... Treatment with the cobalt salts may be carried out at the same time as conventional treatment with an antibiotic and/or proton pump inhibitor." (See abstract). "The cobalt ions may be used together with one or more agents which facilitate targeting together with one or more agents which facilitate targeting to the mucous layer. For example, the cobalt salt may be used together with agents selected from the group consisting of ... mucolytic agents (such as acetylcysteine, guaiphensin or ammonium citrate) ..." (See paragraph 0035). Bruggraber et al. further teach that one common conventional treatment used on *H. pylori* infection is complex triple therapies based on lansoprazole, amoxicillin, and metronidazole. (See paragraph 0019).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

The therapeutic composition taught by Casswall et al. lacks a teaching wherein the composition comprises acetylcysteine as the mucolytic agent. This deficiency is cured by the teachings of Bruggraber et al.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add the bovine colostral hyperimmune immunoglobulin preparation taught by Casswall et al. to the treatment composition taught by Bruggraber et al., as suggested by Bruggraber et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Bruggaber et al. teach that the treatment with cobalt may be carried out at the same time as conventional treatment. Casswall et al. teach that BIC has the ability to inhibit binding of *H. pylori* to gastric mucosa. Therefore, the combined compositions have the additive effect of treating gastrointestinal infections.

The examiner notes that Dial et al. teach that colostrum has lactoferrin. Therefore, it is implicit to the BIC that it also contains an amount of lactoferrin.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
Patent Examiner
Art Unit: 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616